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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,364	08/24/2001	Vincent J . Wacher	AUMX-008/02US	3874

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EXAMINER	
KWON, BRIAN YONG S	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 06/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/914,364	Applicant(s) WACHER ET AL.	
	Examiner Brian S Kwon	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,10-12,14-23,32-36,38-43,52-55 and 57* is/are pending in the application.

4a) Of the above claim(s) *1,10-12,14-22,41,42 and 57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23,32-36,38-40,43 and 52-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. In Applicant's Response filed 5/21/02, Applicant stated that "the Restriction Requirement is inappropriate" since the instant application is related to PCT/US00/05524 in which is subject to a lack of unity of invention rather than US Restriction practice. Examiner inadvertently requires the restriction under US practice instead of a lack of unity of invention under PCT Rule 13.1.

Although Applicant is correct about "no determination of a lack of unity of invention was made" by Examiner, Examiner's original restriction of the instant claims into 2 groups of invention should be aligned with the new restriction requirement under PCT Rule 13.1 (**below**). Therefore, Examiner believes that it is appropriate to examine Group II invention (Claims 23, 32-36 and 38-40) that is directed to formulating an oral pharmaceutical composition comprising a pharmaceutical compound, gallic acid ester and a carrier. In addition, claims 43 and 52-55 will be regrouped as Group II invention in light of the Response. Claims 43 and 52-55 are interpreted as "a method of reformulating an oral pharmaceutical composition...". Accordingly, claims 23, 32-36, 38-40, 43 and 52-55 will be examined as the elected invention. Claims 1, 10-12, 14-22, 41-42 and 57 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 10-12 and 14-22, drawn to a method for increasing bioavailability of an orally administered compound by orally coadministering gallic acid ester.

Group II, claim(s) 23, 32-36 and 38-40, 43 and 52-55, drawn to a formulating an oral pharmaceutical composition comprising a pharmaceutical compound, gallic acid ester and a carrier.

Group III, claim(s) 41-42 and 57, drawn to a composition comprising a pharmaceutical compound, gallic acid ester and a carrier.

The technical feature linking Groups I-III appears to be that they all relate a composition comprising a pharmaceutical compound, gallic acid ester and a carrier (intended purpose of increasing bioavailability of the pharmaceutical compound).

However, Cheng et al. (EP 819433 A2) teaches the use of gallic acid ester (e.g., epigallocatechin gallate, epicatechin gallate) to enhance the activity of antitumor agent (e.g., cytarabine, 5-fluorouracil, methotrexate).

Therefore, the technical feature linking the inventions of Groups I-III does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Accordingly, Groups I-III are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 43 and 52-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 43 and 52-55 are unclear by reciting "A method of increasing bioavailability of the active compound of an existing oral pharmaceutical composition" in claim 43. Although applicant indicates in the Response that claims 43 and 42-55 should be interpreted as a method of "reformulating an oral pharmaceutical composition" instead of Examiner's interpretation of "a method of increasing bioavilability of an orally administered compound...", the recitation of "A method of increasing bioavailability of the active compound of an existing oral pharmaceutical composition" in claim 43 renders the claims (43 and 52-55) unclear whether claims refer to "a method of increasing bioavailability..." or "a method of reformulating an oral pharmaceutical composition...". In view of the differences of the scope of protection which may be attached to the various categories of claims, it must be ensured that wording of a claim leaves no doubt as to its category.

4. Claim 55 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 55 is not clear at all which components should be present in the reformulated oral composition, which generously described as "containing less than all components present in the existing pharmaceutical composition plus the gallic acid ester".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 23, 32-36, 38-40, 43 and 52-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Cheng et al. (EP 819433 A2).

Cheng discloses an enhanced anti-cancer composition prepared by admixing cytarabine (10mg/kg) and epigallocatechin gallate (5-10mg/kg) (see page 3, lines 37-43; Tables 1-3; Claims). The reference teaches or suggests the use of epigallocatechin in improving bioavailability of antitumor agent by reducing metabolism (e.g., oxidation) of the drug in the body (pages 2, lines 11-13 and lines 21-29).

6. Claims 23, 32, 34-36, 38-40, 43, 52 and 54-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Salatinjants (US 4716173).

Salatinjants discloses compositions adapted to prolong the residence time of specified drugs (e.g., sulfa and cinchona alkaloid drugs) in the circulating plasma of humans comprising, among others, tannic acid, thereby enhancing the efficacy of the drug (col. 1, lines 42-44 and 53-61; compositions of Drug No. 1, 2 and 3; col. 4, lines 19-36; claims 1-3". Prolonging the residence time of a drug in the circulating plasma leads to a higher bioavilability of the drug at its target.

7. Although the prior art references are silent about "the gallic acid ester is present in an amount sufficient to produce a concentration of the gallic acid ester in the lumen of the gut of the mammal of at least 0.1 times a Ki or apparent Ki of CYP3A inhibition of the compound" in

claim 34; "at least 10% of the difference between bioavailability in the absence of the gallic acid ester and complete oral bioavailiability" in claim 35; "the gallic acid ester is covalently bound to the pharmaceutical compound in claim 39; and the functional property of "gallic acid ester" as "a counter ion of the pharmaceutical compound" in claim 38, the referenced gallic acid ester (e.g., epigallocatechin gallate) in the claimed range concentration in said composition must inherently possess those properties or characteristics. Therefore, the reference clearly anticipates the claimed invention.

Conclusion

8. No Claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703)308-5377. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brian Kwon

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1600